

**REMARKS**

The Office Action mailed July 29, 2003, has been received and reviewed. Claims 21-44 are currently pending in the application, of which claims 21-33 are under consideration. Claims 34-44 are withdrawn from consideration as being drawn to a non-elected invention, and are accordingly canceled herein. Each of claims 21-33 stand rejected. Claim 30 has been amended, claims 34-44 have been canceled and new claims 45 and 46 have been added as set forth herein. All amendments and cancellations are made without prejudice or disclaimer.

Reconsideration of the application is respectfully requested.

**Rejections under 35 U.S.C. § 112, second paragraph**

Claim 30 stands rejected under 35 U.S.C. § 112, as assertedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, it was thought that claim 30 appears to have incorrect grammar. Applicants have amended claim 30 to address this issue and respectfully submit that this rejection should be withdrawn and the amended claim allowed.

**Rejections under 35 U.S.C. § 103**

Claims 21-33 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Foster (U.S. Pat. 5,485,277) in view of Jackowski (U.S. Pat. 5,747,274). Applicants respectfully traverse the rejections as set forth herein.

M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based

on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The 35 U.S.C. § 103(a) obviousness rejections of claims 21-33 are improper because a *prima facie* case of obviousness has not been established against any of claims 21-33. Specifically, it is respectfully submitted that neither Foster nor Jackowski, taken either in combination or separately, teaches or suggests each and every element of amended independent claim 21.

As amended, independent claim 21 is directed to an assay system for analyzing a biological liquid sample comprising, among other things, a waveguide, a light source, and a light detector. The waveguide is configured to generate an evanescent field at least one surface thereof as light is directed therein. The waveguide also includes capture molecules for at least one indicator of coronary artery disease on at least one planar surface thereof. The capture molecules are for at least one indicator of coronary artery disease. The light detector detects fluorescent light emitted as fluorescently labeled tracer molecules, which indicate binding of the at least one indicator of coronary artery disease by a capture molecule, are excited by the evanescent field.

The Office Action indicates "Foster discloses the invention substantially as claimed" (Office Action of July 29, 2003, page 3), except for the at least one indicator of coronary artery disease. Actually, the teachings of Foster are limited to surface plasmon resonance ("SPR") system, which, as is well known in the art, includes a waveguide with a thin layer of metal on at least one surface thereof. *See, e.g.*, Foster, col. 1, lines 14-58; col. 5, lines 10-27; Jackowski, col. 28, lines 21-25. Light that is incident upon the thin metal film couples into surface nodes, which are associated with oscillations of electrons in the thin metal film. *See, id.* If capture molecules on the thin metal layer have bound analyte, the angular position of SPR changes. *See*, Foster, col. 5, lines 10-27. Measurements of the change in the change of SPR, which are obtained from a detector positioned to face the thin metal layer (*i.e.*, the oscillations of electrons are not detected through the waveguide), are used to measure the presence or absence of the analyte, as well as levels of the analyte that are present in a sample. *See, id.*

As stated in Foster “the SPR resonance position [is] measured,” wherein “[t]he dark bands, 250, shown toward the right side of FIGS. 8(a) and 8(b) correspond to those rays that couple to the surface plasmon resonance and are thus attenuated. The focused beam, 251, is refracted, 252, when it enters the waveguide, 60. The position of the attenuated band is monitored by a CCD array. As the surface plasmon resonance position shifts, the dark band sweeps across the CCD array in proportion to the concentration of target analyte that binds to the recognition layer.” Foster, col. 10, lines 62-63; col. 10, line 65, to col. 11, line 6.

Foster lacks any teaching or suggestion that the system therein includes a waveguide which is configured to generate an evanescent field. The presence of the thin metal film on the capture molecule-bearing surface of the waveguide of Foster would actually prevent the generation of an evanescent field at that surface. Thus, Foster cannot teach or suggest that the CCD array thereof detects “fluorescent light emitted as fluorescently labeled tracer molecules, which indicate binding of the at least one indicator of coronary artery disease by a capture molecule, are excited by the evanescent field,” as recited in amended independent claim 21.

Jackowski also fails to teach or suggest a light detector which detects “fluorescent light emitted as fluorescently labeled tracer molecules, which indicate binding of the at least one indicator of coronary artery disease by a capture molecule, are excited by the evanescent field.” Although Jackowski teaches that both SPR-type waveguides and optical waveguides may be used, the teachings of Jackowski are limited to optical waveguide systems in which fluorescent molecules are excited by a light detector which is external to the waveguide, then coupling the fluorescence into the waveguide. Col. 28, lines 15-20. Then, fluorescent that is emitted from bound molecules is detected differentially, or discriminated, from fluorescence that is emitted from unbound molecules. Col. 28, lines 17-20. This differential detection is effected by the “angular divergence” of fluorescent signals as they exit the waveguide. *Id.*

The nonobviousness of independent claim 21 precludes a rejection of each of claims 22-33 and new claims 45 and 46 which depend therefrom because a dependent claim is obvious only if the independent claim from which it depends is obvious. (*See In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988), *see also* M.P.E.P. § 2143.03).

Accordingly reconsideration and withdrawal of the obviousness rejections of claims 21-33 are respectfully requested, as is the entry and allowance of new claims 45 and 46.

### CONCLUSION

All pending claims are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Office determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

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